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BAF-16802/29

In re Application of: Bret A. Ferree

Application No.
10/767,194-Conf. #5735Filing Date
January 29, 2004Examiner
A. J. StewartGroup Art Unit
3738

Invention: IN SITU ARTIFICIAL DISC REPLACEMENTS AND OTHER PROSTHETIC COMPONENTS

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Dated: August 29, 2007

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of: Ferree

Serial No.: 10/767,194

Group No.: 3738

Filed: January 29, 2004

Examiner: A. J. Stewart

For: IN SITU ARTIFICIAL DISC REPLACEMENTS AND OTHER PROSTHETIC
COMPONENTS

APPELLANT'S BRIEF UNDER 37 CFR §41.37

Mail Stop Appeal Brief
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I. Real Party in Interest

The real party and interest in this case is Bret A. Ferree, Applicant and Appellant.

II. Related Appeals and Interferences

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

The present application was filed with 21 claims. Claims 3, 4 and 9-12 have been withdrawn from consideration. Claims 6, 16 and 21 have been canceled. Claims 1-5, 7-15 and 17-20 are pending; however, claims 1, 2, 5, 7, 8, 13-15 and 17-20 are rejected and under appeal. Claims 1 and 18 are the independent claims.

**IV. Status of Amendments Filed Subsequent
Final Rejection**

No after-final amendments have been filed.

V. Summary of Claimed Subject Matter

Independent claim 1 is directed to an artificial disc replacement (ADR) apparatus, comprising an endplate having a surface that articulates with a cooperating component; and wherein surface of the endplate is formed with separate components that are physically configured for assembly within an intervertebral disc space. (*See, for example*, Specification at page 7, line 8 to page 8, line 27; Figures 3A-10).

Independent claim 18 is directed to a method of implanting an artificial disc replacement (ADR) into an intervertebral disc space, comprising the steps of providing an endplate constructed from first and second components; installing the first component into an intervertebral disc space; and installing the second component into the disc space by attaching the second component to the first component, thereby assembling the endplate *in situ*. (*See, for example*, Specification at page 7, line 8 to page 8, line 27; Figures 3A-10).

VI. Grounds of Objection/Rejection To Be Reviewed On Appeal

A. The rejection of claims 1, 2, 5, 8, 13-15 and 17-20 under U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,692,495 to Zacouto.

B. The rejection of claim 7 under 35 U.S.C. §103(a) over U.S. Patent No. 6,692,495 to Zacouto.

C. The rejection of claim 17 under U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,692,495 to Zacouto.

D. The rejection of claims 18-20 under U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,692,495 to Zacouto.

VII. Argument

A. Claims 1, 2, 5, 8, 13-15 and 17-20.

Claims 1, 2, 5, 8, 13-15 and 17-20 under U.S.C. §102(e) over U.S. Patent No. 6,692,495 to Zacouto. It is Appellant's position, however, that the Examiner is erroneously combining two separate embodiments of the '495 Patent into a single embodiment. The first embodiment is described with

reference to Figures 14 and 15 of the '495 patent. The second embodiment is shown in Figure 16. All are reproduced below:

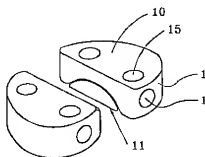


FIG. 14

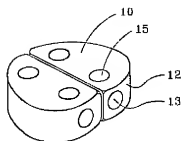


FIG. 15

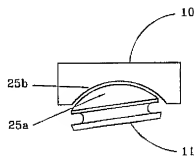


FIG. 16

In the embodiment of Figures 14 and 15, Appellant concedes that two components are being coupled together according to the Zacouto reference. "With reference to FIGS. 14 and 15, the two fixators F advantageously have complementing shapes so that once they have been fitted, they can form a geometrically coherent entity, such as an all-in-one piece (FIG. 15)." ('495 Patent; 8:34-37). But in this embodiment, item 11 is a "plate" and not an articulating component. This is evident for several reasons. First, the bottom of item 11 is flat and flush with the bottom of item 10, thereby precluding any pivoting movement.

Second, Zacouto explains that "the two plates 10, 11 and the bellows 25 (not visible) are introduced all together into the intervertebral space V." ('495 Patent; 8:21-24). This bellows 25, shown in Figure 1 of the '495 patent, for example, would go right through the plates 10, 11, further preventing

articulation. Further, Zacouto states that, *in this embodiment*, “[i]t is possible that more than two fixators might be provided in each intervertebral space, for example four fixators might be provided.” (‘495 Patent; 8:36-40). Clearly if four such “fixators” are used articulation would be impossible. Thus, in summary, although Zacouto does disclose component assembly, it is the assembly of “fixator” components as opposed to articulating components.

Turning to the second embodiment of Zacouto shown in Figure 16, Zacouto states that “[t]he moving and/or deformable elements of the intermediate element may be produced in some form other than the form of bellows. Thus, as depicted diagrammatically in FIG. 16, it is possible to use complementary curved (convex or concave) surfaces 25a, 25b capable of sliding one on the other in a sliding space.” (‘495 Patent; 8:45+) However, in this embodiment, the plate 10 (in Figure 16) is disclosed as having been assembled in a disc space; rather, it is seen, and would be understood to the person of skill in the art, as a unitary piece. *The fact that Zacouto uses numerical references 10 and 11 (for example) in Figures 14-16 is irrelevant.* Zacouto calls many different components parts “10” or “11” (See Figures 1 and 18)

Thus, the embodiment of Figures 14, 15 of Zacouto, and the embodiment of Figure 16, are mutually exclusive and should not be combined for the purposes of rejection. Zacouto does not set forth an enabling, unified disclosure that teaches each and every element of Appellant’s invention as claimed. Accordingly, prima facie anticipation has not been established. Anticipation may be established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. RCA Corp. v. Applied Digital Data Systems, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). Moreover, anticipation requires the presence of all elements of a claimed invention as arranged in the claim, such that a disclosure “that ‘almost’ meets that standard does not ‘anticipate.’” Connell v. Sears, Roebuck Co., 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983).

B. Claim 7

Claim 7 adds to claim 1 that “each of the separate components are press-fit into a vertebral body.” The claim stands rejected under 35 U.S.C. §103(a) over Zacouto on the grounds that a “press-fit” engagement could somehow replace a “snap-fit” engagement. (Final OA, top of p. 4) However, the

Examiner is confusing two types of “engagement.” “Snap-fit” refers to the way in which Appellant’s endplate components are connected, as shown, for example, in Figure 3B of the instant specification. “Press-fit” refers to the way in which each of the separate components are press-fit *into a vertebral body*. This is accomplished with the vertically oriented spikes shown, for example, in Figure 3A. These spikes, when press-fit into a vertebral body, enhance fixation and help to prevent migration. Thus, they are used for a particular purpose to solve a stated problem, contrary to the Examiner’s argument.

Nor would it be obvious to replace Zacouto’s vertebral interconnection system with Appellant’s press-fit components, since this would change one of Zacouto’s principles of operation. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)

C. Claim 17.

Claim 17 adds to claim 1 the limitation that the spacer is contained within a disc space using a mesh or elastic component. Although claim 17 stands rejected under U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,692,495 to Zacouto, the Examiner’s only argument is “see Fig. 1. The bellows can be called spacers [sic] because the space [sic] the two intervertebral plates (11).” Final OA, p. 3. Apart from being nearly incomprehensible, no mention is made of a “mesh or elastic component” and Appellant’s endplate has a surface *that articulates with a cooperating component*. For at least these reasons the Examiner has failed to establish *prima facie* anticipation.

D. Claim 18.

Method claims 18-20 stand rejected under U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,692,495 to Zacouto based upon the argument “[s]ee Figs. 1-18, see cols. 6-8.” Final OA, p. 3. Well, Appellant has “seen” *all of the Figures* of Zacouto and has “seen” cols. 6-8, and has concluded that the e method steps are neither taught nor suggested. Appellant respectfully requested that the Examiner point precisely where in all of the figures and three entire columns of Zacouto one may find the limitations of the subject claims, but no further details were provided.

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellant seeks the Board's concurrence at this time.

Respectfully submitted,

By: _____

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APPENDIX A

CLAIMS ON APPEAL

1. Artificial disc replacement (ADR) apparatus, comprising:
an endplate having a surface that articulates with a cooperating component; and
wherein surface of the endplate is formed with separate components that are physically configured for assembly within an intervertebral disc space.
2. The ADR apparatus of claim 1, wherein:
the endplate, or the endplate and the cooperating component, are composed of dissimilar materials.
5. The ADR apparatus of claim 1, wherein:
the endplate includes an articulating component composed of chrome cobalt or another metal alloy.
7. The ADR apparatus of claim 1, wherein each of the separate components are press-fit into a vertebral body.
8. The ADR apparatus of claim 1, wherein the separate components are connected through a snap-fit engagement.
13. The ADR apparatus of claim 1, wherein the cooperating component is a spacer that is not rigidly connected to the endplate.
14. The ADR apparatus of claim 13, wherein the spacer is rotated or otherwise manipulated to achieve a vertebral distraction function.
15. The ADR apparatus of claim 13, wherein the spacer is contained within a disc space

using a clip or other retaining element.

17. The ADR apparatus of claim 13, wherein the spacer is contained within a disc space using a mesh or elastic component.

18. A method of implanting an artificial disc replacement (ADR) into an intervertebral disc space, comprising the steps of:

providing an endplate constructed from first and second components;
installing the first component into an intervertebral disc space; and
installing the second component into the disc space by attaching the second component to the first component, thereby assembling the endplate *in situ*.

19. The method of claim 18, wherein the first and second components are comprised of dissimilar materials.

20. The method of claim 18, further including a spacer component which is also assembled *in situ*.

APPENDIX B

EVIDENCE

None.

APPENDIX C

RELATED PROCEEDINGS

None.